I

108TH CONGRESS
1ST SESSION

H. R. 3155

To amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs that fail to provide certain information or to present information in a balanced manner, and to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 2003

Mr. STARK (for himself, Mr. EMANUEL, and Mr. GRIJALVA) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs that fail to provide certain information or to present information in a balanced manner, and to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Fair Balance Prescription Drug Advertisement Act of 2003''.

SEC. 2. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUG THAT FAILS TO PROVIDE CERTAIN INFORMATION OR TO PRESENT BALANCED INFORMATION.

(a) GENERAL RULE.—Part IX of subchapter B of chapter 1 of the Internal Revenue Code of 1986 (relating to items not deductible) is amended by adding at the end thereof the following new section:

''SEC. 280I. DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUG THAT FAILS TO PROVIDE CERTAIN INFORMATION OR TO PRESENT BALANCED INFORMATION.

''No deduction shall be allowed under this chapter for any expense of an advertisement for a prescription drug if, with respect to such advertisement, the Secretary of Health and Human Services has submitted to the Secretary of the Treasury a report under section 311 of the Federal Food, Drug, and Cosmetic Act.''

(b) CLERICAL AMENDMENT.—The table of sections for part IX of subchapter B of chapter 1 of such Code is amended by adding at the end thereof the following new item:

''Sec. 280I. Direct-to-consumer advertisement of prescription drug that fails to provide certain information or to present balanced information.''

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred after December 31, 2003.

SEC. 3. PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING; REPORTING OF VIOLATIONS TO INTERNAL REVENUE SERVICE.

Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is amended by adding at the end the following section:

''PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING; REPORTING OF VIOLATIONS TO INTERNAL REVENUE SERVICE

''SEC. 311. With respect to a direct-to-consumer advertisement of a prescription drug, the Secretary shall report to the Secretary of the Treasury—

''(1) any violation of section 301 involving the misbranding of the prescription drug by reason of failure to comply with the requirements of section 502(n) that relate to the provision in the advertisement of true statements relating to side effects, contraindications, and effectiveness; or

''(2) any determination by the Secretary, made upon a petition of an interested person or the Sec-

retary's own initiative, that under criteria established by the Secretary by regulation, the portion of the advertisement devoted to describing side effects, contraindications, or any lack of effectiveness is less than the portion of the advertisement devoted to describing the benefits of the drug, taking into account the amount and type size of any printed information, whether all printed material is printed together or on facing or consecutive pages, the duration of the advertisement (in the case of an advertisement through media such as television or radio), and such other factors as the Secretary determines to be appropriate.''.

○